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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Albert K. Chin

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EXAMINER

SMITH, PHILIP ROBERT

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

11/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/696,381	Applicant(s) CHIN, ALBERT K.	
	Examiner PHILIP R. SMITH	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112, Paragraph One

- [01] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [02] Claims 27-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
- [02a] With regard to claim 27: the specification does not refer to an outer sheath that has “a distal tip for dissecting tissue.” In each of the methods described, the tissue expansion device has a distal tip for dissecting tissue, which expands the outer sheath when it is subsequently withdrawn.
- [02b] With regard to claim 29: the specification does not refer to a distal tip [of an elongated instrument] that is “fixedly secured to a distal end of the outer sheath.”
- [02c] With regard to claim 31: the specification does not refer to an expansion device that is prevented from moving distal to the distal tip of the outer sheath.

Claim Rejections - 35 USC § 103

- [03] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [04] Claims 15, 21-23, 25-31 & 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (5,318,588) in view of Chin (6,264,670).
- [05] With regard to claim 15:

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[05a] Horzewski discloses an apparatus for performing a surgical procedure, comprising:

- an elongated instrument (“dilator 150” 12/49) having a distal tip (“bulbous region 127” 12/64) configured to dissect tissue;
- an outer sheath (“side arm sheath 90” 11/67) disposed about at least a portion of the elongated instrument, the outer sheath having a distal portion that is expandable in an outward direction (“accommodate positive radial expansion over a specific range of radial dimensions” 12/7-9) in response to a relative movement between the elongated instrument and the outer sheath (“Withdrawal of the dilator [150]... through the confines of the sheath increases the profile of the delivery channel to the desired profile as bulbous region 127 is withdrawn through the shaft” 13/12-15).

[05b] Horzewski does not disclose that the distal tip is transparent.

[05c] Chin discloses a tissue dissection method wherein an elongated instrument has “a detachable, transparent blunt tip 903.” At the time of the invention, it would have been obvious to a person of ordinary skill in the art to provide the transparent tip disclosed by Chin on the dilator disclosed by Horzewski. A skilled artisan would be motivated to do so in order to enable viewing through the dissecting tip.

[06] With regard to claim 21: As noted above, the distal tip is placeable distal to the distal portion of the outer sheath, and the distal tip has an outer dimension that is larger than an outer dimension of the outer sheath when the distal tip is distal to the distal portion of the outer sheath.

[07] With regard to claim 22: As noted above, the distal portion of the outer sheath is configured to push the dissected tissue away from a longitudinal axis of the elongated instrument.

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- [08] With regard to claim 23: the elongated instrument disclosed by Horzewski comprises an endoscopic lumen for housing an endoscope (“guidewire channel 122”).
- [09] With regard to claim 25: as noted above, the tissue is next to a vessel, and the outer sheath is configured to push the dissected tissue away from a longitudinal axis of the elongated instrument to create a tunnel next to the vessel.
- [10] With regard to claim 26: Horzewski discloses that the elongated instrument comprises an expansion device located proximal to the distal end (the most bulbous portion of “127”; see Figure 6B).
- [11] With regard to claim 27: As noted above, Horzewski in view of Chin discloses an apparatus for performing a surgical procedure, comprising:
- [11a] an elongated instrument having an expansion device;
 - [11b] an outer sheath disposed about at least a portion of the elongated instrument, wherein the outer sheath is expandable in an outward direction in response to a relative movement between the elongated instrument and the outer sheath.
- [12] With regard to claim 28: As noted above, Horzewski in view of Chin discloses that the distal tip has a tapered configuration and is transparent.
- [13] With regard to claim 29: As noted above, Horzewski discloses an outer sheath.
- [14] With regard to claim 30: As noted above, Horzewski discloses that the outer sheath is configured to push the dissected tissue away from a longitudinal axis of the elongated instrument.
- [15] With regard to claim 31: As noted above, Horzewski discloses that the expansion device is housed within a lumen of the outer sheath, and is prevented from moving distal to the distal tip of the outer sheath.

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- [16] With regard to claim 34: As noted above, Horzewski discloses that the tissue is next to a vessel, and the outer sheath is configured to push the dissected tissue away from a longitudinal axis of the elongated instrument to create a tunnel next to the vessel.
- [17] With regard to claim 35: As noted above, Horzewski discloses that the elongated instrument comprises an endoscopic lumen for housing an endoscope.

Additional Claim Rejections - 35 USC § 103

- [18] Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (5,318,588) in view of Chin (6,264,670) and in further view of Vandegrift (2,201,749).
- [19] With regard to claim 16:
- [19a] Horzewski in view of Chen discloses an outer sheath having a distal portion, as noted above.
- [19b] Horzewski in view of Chen does not disclose that the distal portion of the outer sheath includes a first free end and a second free end.
- [19c] Vandegrift discloses an expanding vein tube which is "split vertically throughout the greater portion of its length along diametrically opposed lines as at 2,2 which provide semi-circular legs 3 and 4" (1/51-54). The tube disclosed by Vandegrift accomplishes a similar function to that of Horzewski in view of Gibson: expansion of an outer shell in response to a "plunger" or "dilator" being passed through it.
- [19d] At the time of the invention, it would have been obvious to a person of ordinary skill in the art that an outer shell having two half cylindrical segments configured to expand in response to a dilator ("3 and 4" as disclosed by Vandegrift) be substituted for the outer

sheath disclosed by Horzewski. A skilled artisan would be motivated to do so in order to provide for simpler manufacturing of the device.

- [20] With regard to claim 17: As noted above, Vandegrift discloses that the first free end and the second free end are configured to move away from each other in response to the relative movement between the elongated instrument and the outer sheath.
- [21] With regard to claim 18: As noted above, Vandegrift discloses that the first free end is a part of a half cylindrical segment, and the second free end is a part of another half cylindrical segment.
- [22] With regard to claim 19: As noted above, Vandegrift discloses that the distal portion of the outer sheath is expandable in response to placement of the distal tip of the elongated instrument between the first free end and the second free end.
- [23] With regard to claim 20: Vandegrift discloses a resilient connector for urging the first free end and the second free end towards each other ("the tube is made of resilient material" 1/55).

Additional Claim Rejections - 35 USC § 103

- [24] Claims 24 & 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (5,318,588) in view of Chin (6,264,670) and in further view of Lehrer (5,685,856).
- [25] With regard to claim 24:
- [25a] Horzewski in view of Chin does not disclose a handle eccentrically attached near a proximal end of the outer sheath.
- [25b] Lehrer discloses in 12/51-58 (see Figures 1A and 3A) a "handle 120" wherein "Handle offset 118 offsets handle 120 to the side of sleeve guide 104 and is adjustable via knob 122 to vary the distance between distal handle end 124 and the distal tip of sleeve guide 104. By adjusting knob 122, the surgeon can vary the depth of penetration of the device

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into the body cavity by holding the handle at the distal end and against the surface of the abdominal wall. An advantage of this procedure is that accidental injuries due to over penetration can be avoided.

[25c] At the time of the invention, it would have been obvious to a person of ordinary skill in the art to provide the handle disclosed by Lehrer on the apparatus disclosed by Horzewski in

[25d] view of Chin. A skilled artisan would be motivated to do so in order to avoid "accidental injuries due to over penetration," as noted above.

[26] With regard to claim 32: As noted above, Horzewski in view of Chin and Lehrer discloses a handle eccentrically attached near a proximal end of the outer sheath.

[27] With regard to claim 33: the handle disclosed by Lehrer is inherently "detachably attached" to the proximal end of the outer sheath.

Conclusion

[28] Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

[29] A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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- [30] Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHILIP R. SMITH whose telephone number is (571)272-6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.
- [31] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.
- [32] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Philip R Smith/

Examiner, Art Unit 3739

/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739